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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/678,751

10/06/2003

Andrea Pahmeier

2923-570

6589

6449

7590

01/12/2005

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/678,751

Applicant(s)

PAHMEIER ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-113 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 51-113 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>01/05/05</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Examiner acknowledges receipt of amendment to the claims, replacement drawing Figure 2 submitted in response to Draftsperson's objections of the drawings and remarks, all filed 08/25/04. The issues raised under 35 USC 112 are no longer relevant because the original claims are cancelled and new claims 51-113 are added. The amendment, which results in presentation of method claims that are directed to methods for culturing cells leads to requirement for restriction and election below.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 51-62, 77-84, 89 and 90, drawn to chitosan and acid based matrix, classified in class 424, subclass 464.
 - II. Claims 63-73, 85, 91-100, 104-106 and 110, drawn to method for culturing cells, classified in class 435, subclass 366.
 - III. Claims 74, 86, 107 and 111, drawn to method for repairing cartilage or bone defect, classified in class 424, subclass 423.
 - IV. Claims 75, 87, 108 and 112, drawn to method for replacing a microcapillary, classified in class 424, subclass 423.
 - V. Claims 76, 88, 109 and 113, drawn to method for providing a filler material during surgery, classified in class 424, subclass 423.
 - VI. Claims 101-103, drawn to method for producing a matrix, classified in class 435, subclass 235.1.

The inventions are distinct, each from the other because of the following reasons:

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2. Inventions II-VI and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case cells can be cultured in medium that is different from the matrix of claim 51.
3. The method of culturing cells in Group II differs from method for repairing cartilage or bone defect of Group III, and the cartilage or bone defect can be repaired with matrix other than the matrix used in Group II.
4. The method of culturing cells in Group II and the method for repairing cartilage or bone defect of Group III differ from the method for replacing a microcapillary of Group IV, and a microcapillary can be replaced by different method and different matrix used in Groups II and III.
5. The method of culturing cells in Group II and the method for repairing cartilage or bone defect of Group III and the method for replacing a microcapillary of Group IV differ from the method for providing filler material during surgery of Group V, and a filler material different than that of the matrix of Groups II, III and IV can be used during surgery.
6. The method of culturing cells in Group II and the method for repairing cartilage or bone defect of Group III and the method for replacing a microcapillary of Group IV and the method of providing filler material during surgery of Group V differ from the method of producing a matrix in Group VI. The process/method as claimed in Group VI can be used to make other and materially different product or (2) that the product as claimed can be made by another and

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materially different process (MPEP § 806.05(f)). Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. The method claims are directed to various cell types and the bioreactor filling material produces many cell types and the matrix can be single or multilayered.

If applicants elect group I, applicants must further elect the form of the matrix for prosecution, a matrix in the form of sheet or hollow article or roll must be elected.

If applicants elect Group II, applicants must elect a specific type of cell from cartilage, bone, blood vessel tissue, skin, nerve tissue and blood stem cells. If applicants elect Group II, applicants must further elect a specific type of cell that is produced from the bioreactor filling material, the specific cell type must be elected from proteins, cells, and viruses. Applicants must further elect capillary generation, artificial organ generation or skin system generation as provided by the matrix. Applicants must also elect single or multilayered matrix and sterilized or non-sterilized matrix since the matrix in claim 91 encompasses sterilized matrix and matrix that is not sterilized.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. A telephone call was made to attorney Patrick T. Skacel on January 4, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

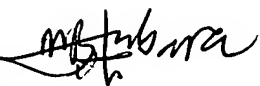
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read 'Blessing Fubara', is written over the printed name.